

AMENDMENTS TO THE CLAIMS

1-52. (Cancelled)

52. (Currently Amended) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet consisting of progesterone as the active ingredient, pharmaceutically acceptable excipients or diluents, and an effervescent, and retaining said tablet in the vagina for a time efficacious to deliver said progesterone to said patient.

53. (Allowed, Previously Presented) A method according to claim 52, wherein the progesterone in said tablet is present in an amount of at least 50 mg.

54. (Allowed, Previously Presented) A method according to claim 53, wherein said placing of tablet is effected as part of a twice-daily dosing regimen.

55-105. (Cancelled)

106. (Currently Amended) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet consisting of progesterone, a pharmaceutically acceptable excipients ~~or diluent~~, and an effervescent, wherein said tablet is prepared by the steps of:

(i) mixing water with progesterone to obtain wetted progesterone in the absence of a pharmaceutically acceptable excipients or diluents; and drying said wetted progesterone to form dry progesterone;

(ii) mixing said dry progesterone with

(a) a pharmaceutically acceptable excipients or diluents and

(b) an effervescent to form a mixture; and

(iii) forming the tablet by direct compaction of said mixture,

and retaining said tablet in said vagina until the tablet dissolves, wherein the tablet provides a T_{max} ~~upon dissolution of about three hours~~ between about 3.1 hours to about 10.0 hours after said tablet is placed in the vagina.

107. (Allowed, Previously Presented) A method according to claim 106, wherein the progesterone in said tablet is present in an amount of at least 50 mg.

108. (Allowed, Previously Presented) A method according to claim 106, wherein said placing of said tablet is effected as part of a twice daily dosing regimen.

109-113. (Cancelled)

114. (Allowed, Previously Presented) The method of claim 52, wherein the progesterone in said tablet is present in an amount of at least about 100 mg.

115. (Allowed, Previously Presented) The method of claim 52, wherein the effervescent in the tablet is present in an amount of about 5% to about 12% by weight of the tablet.

116. (Allowed, Previously Presented) The method of claim 115, wherein the effervescent in the tablet is present in an amount of about 8% by weight of the tablet.

117. (Allowed, Previously Presented) The method of claim 52, wherein said placing of said tablet is effected as part of a twice-daily dosing regimen.

118. (Allowed, Previously Presented) The method of claim 52, wherein the progesterone is micronized progesterone.

119. (Allowed, Previously Presented) The method of claim 106, wherein the progesterone is micronized progesterone.

120. (Allowed, Previously Presented) The method of claim 106, wherein the progesterone in said tablet is present in an amount of about 100 mg.

121. (Currently Amended) A method of delivering progesterone to a female patient, which method comprises

(a) placing in the vagina of the patient a vaginal tablet consisting of micronized progesterone as the active ingredient, pharmaceutically acceptable excipients or diluents, and an effervescent; and

(b) permitting the tablet to dissolve in the vagina,

the tablet providing a T_{max} ~~of about 3 hours upon dissolution~~ between about 3.1 hours to about 10.0 hours after said tablet is placed in the vagina.

122. (Allowed, Previously Presented) A method of delivering progesterone to a female patient, comprising placing in the vagina of the patient a tablet consisting essentially of micronized progesterone, colloidal anhydrous silica, maize starch, povidone, lactose, adipic acid, sodium bicarbonate, magnesium stearate, and sodium lauryl sulfate.

123. (Currently Amended) The method of claim 122, wherein the tablet consists essentially of about 8 wt. % dry micronized progesterone, about 0.2 wt. % colloidal ~~anhydrous~~ anhydrous silica, about 16.8 wt. % maize 1500 starch, about 4.0 wt. % povidone 30, about 60.8 wt. % lactose, about 4.5 wt. % adipic acid, about 3.4 wt. % sodium bicarbonate, about 1.8 wt. % magnesium stearate, and about 0.4 wt. % sodium lauryl sulfate.

124. (New) The method of claim 52, wherein the tablet provides a mean peak plasma level (T_{max}) of progesterone in said patient between about 3.1 hours to about 10.0 hours after said tablet is placed in the vagina.

125. (New) The method of claim 124, wherein the tablet provides a mean peak plasma level (T_{max}) of progesterone in said patient between about 3.8 hours to about 8.7 hours after said tablet is placed in the vagina.